



NEW YORK MEDICAL COLLEGE

DEPARTMENT OF MEDICINE, DIVISION OF INFECTIOUS DISEASES
WESTCHESTER MEDICAL CENTER

VALHALLA, NEW YORK 10595 TEL: 914-493-8865 FAX: 914-493-7289 FAX: 914-594-4673

February 16, 2006

Michael C. Colville
 Assistant U.S. Attorney, Civil Division
 United States Attorney
 Western District of Pennsylvania
 U.S. Post Office and Courthouse
 700 Grand St./Suite #4000
 Pittsburgh, PA 15219

RE: Mark E. Fix vs. U.S.A.
 C.A.#: 04-97E

Dear Mr. Colville:

In regard to the above captioned case, I have reviewed the materials that you sent to me, which included:

Response of Defendant to Plaintiff's interrogatories.

Exhibit A - Affidavit.

Exhibit B - memo from Ronald K. Smith D.O. to Lawrence D. Kerr, undated, but executed September 21, 2004.

Exhibit C - Clinical Laboratory report dated 6/21/2000.

Exhibit D - 11/8/02 letter from Joseph J. Joseph, M.D., to Mr. Mark Fix.

Exhibit E - Claim for damage, injury, or death, date of claim 5/27/03.

Exhibit F - 10/7/03 letter to Lawrence D. Kerr from Henry J. Sadowski.

Medical records of Mr. Fix provided by Dr. Joseph.

MRI of brain dated 12/7/2000.

CT brain and orbits 5/29/2000.

Bradford Regional Medical Center ER records regarding Mr. Fix 5/29/2000.

J. Stephen Shymansky, M.D. medical records regarding Mr. Fix.

Seneca eye surgeons medical records regarding Mr. Fix dated 6/22/00, 6/8/00, 6/2/00.

Mayo Clinic records regarding Mr. Fix.

GARY P. WORMSER, M.D., CHIEF, PROFESSOR OF MEDICINE AND PHARMACOLOGY

ROBERT B. NADELMAN, M.D., PROFESSOR OF MEDICINE

HAROLD W. HOROWITZ, M.D., PROFESSOR OF MEDICINE

MARISA MONTECALVO, M.D., ASSOCIATE PROFESSOR OF MEDICINE

CATHERINE B. SMALL, M.D., ASSOCIATE PROFESSOR OF MEDICINE

JOHN NOWAKOWSKI, M.D., ASSOCIATE PROFESSOR OF MEDICINE

CHARLES PAVIA, PH.D., ASSOCIATE PROFESSOR OF MEDICINE

GEORGE SAKOULAS, M.D., ASSISTANT PROFESSOR OF MEDICINE

GOVERNMENT
EXHIBIT

"A"

Records from Forbes Regional Hospital regarding Mr. Fix.

Over 650 numbered records which included:

- A. Records from the FCI Loretto;
- B. Records from the FCI at McKean, Bradford, PA;
- C. Records from Forbes Regional Hospital;
- D. Records from Bradford Regional Medical Center Emergency Room.

Case Review

Mr. Mark Fix was born on 9/28/56. From 2/17/99 to 9/21/01 he was incarcerated in Federal Prison. The relevant aspects of his medical history regarding a possible diagnosis of Lyme disease and other infectious diseases are as follows:

On 5/12/00 he first noted a skin lesion on his right lower extremity. He did not note a tick bite.

On 5/15/00 he was examined at the prison medical facility and found to have a nasolabial herpes simplex type lesion ("cold sore"), for which he was prescribed oral acyclovir. Two small erythematous lesions were observed on the right lower extremity. A diagnosis of a spider bite or dermatitis was entertained and topical steroids prescribed.

On 5/27/00 Mr. Fix noted reduced vision of his left eye.

On 5/29/00 an eye examination was recorded by Gracia Fairbands, MLP. An eye examination was also performed in an emergency room visit at Bradford Regional Medical Center. Oral and topical steroids were prescribed. A cranial CT scan showed an air-fluid level in the left maxillary sinus.

On 5/30/00 Dr. Keller diagnosed optic neuritis.

On 6/8/00 Dr. O'Brien diagnosed optic neuritis.

On 6/21/00 a Lyme ELISA showed low positivity without any bands on IgG or IgM immunoblots.

On 7/5/00 carotid doppler studies were normal.

On 10/19/00 trimethoprim-sulfamethoxazole was prescribed for sinusitis.

On 11/29/00 the patient noted a reduction in vision in the right eye.

On 11/30/00 a diagnosis of optic neuritis of the right eye was suggested by Dr. James Repko. Optic disks were noted to be flat. Mr. Fix was given 1 dose of steroids.

On 12/7/00 a cranial MRI showed foci of increased signal intensity in the white matter with enhancement in some of the foci with a subtle increase in signal intensity in the left optic chiasm (at Altoona Hospital).

By 12/19/00 there was further loss of vision of the right eye. A neurologist diagnosed probable multiple sclerosis.

On 1/6/01 a 10 day course of amoxicillin, 250 mg orally three times per day, was prescribed for sinusitis.

On 1/25/01, there was a positive EIA including a positive IgM EIA but only 1 significant band on IgG immunoblot and no significant bands on IgM immunoblot.

On 2/1/01 Mr. Fix began an 8 week course of oral antibiotics for Lyme disease, approximately 5 weeks of doxycycline (100 mg twice daily) followed by approximately 3 weeks of amoxicillin (500 mg three times daily). The change to amoxicillin occurred because of gastrointestinal upset from the doxycycline.

By 2/9/01 equilibrium problems and staggering were noted in the medical records. At some point Mr. Fix also developed numbness and weakness of his legs which improved by 2/23/01.

On 3/29/01 Mr. Fix refused a spinal tap.

By 4/10/01 the patient complained of generalized weakness, left leg numbness, left arm numbness, and poor gait coordination.

On 4/30/01 Mr. Fix was evaluated by Dr. Wilson, a well-known infectious disease specialist at the Mayo Clinic. He elicited a history from Mr. Fix that he had had two approximately 1 cm pruritic skin lesions in May 2000.

On 5/7/01 a cerebrospinal fluid (CSF) examination showed a negative Lyme PCR (polymerase chain reaction), an elevated protein level of 75, and positive tests for oligoclonal banding and for myelin basic protein.

On 5/10/01, a sample of either serum or CSF tested negative for Lyme by an ELISA.

On 5/25/01, a cranial MRI showed abnormalities. The optic chiasm and optic tracts had an abnormal T-2 signal.

Since 12/19/01, Mr. Fix has been treated extensively, apparently for many months, with antibiotics for Lyme disease by Dr. Joseph, including approximately 10 weeks of IV ceftriaxone.

On 10/15/02 a positive IgM immunoblot with a negative IgG immunoblot was recorded. No ELISA was reported.

Summary and Conclusions

Clinically, Mr. Fix has suffered sequential episodes of optic neuritis leading to a reduction in visual acuity in both eyes. Both CSF testing and cranial MRIs have shown abnormalities. The patient has been treated extensively for Lyme disease.

Optic neuritis is an exceptionally rare manifestation of Lyme disease. In one study of 440 patients with optic neuritis evaluated at the Stony Brook University Medical Center in Long Island New York, only 1 case could be confidently attributed to Lyme disease (J Neuro-ophthalmol 2005;25:71-82). This medical center is located in a county highly endemic for Lyme disease in New York State, which is the state with the highest incidence of Lyme disease in the United States.

Skin lesions commonly occur in Lyme disease, and Mr. Fix had skin lesions but the descriptions of these were not at all suggestive of Lyme disease. Furthermore, he did not test positive for Lyme disease at any time using recommended testing criteria. Mr. Fix had a positive Lyme ELISA, but positive serologic testing for Lyme disease requires positivity by both ELISA and immunoblot. This is necessary due to the low specificity of the Lyme ELISA and has been the standard of practice since the Centers for Disease Control and Prevention recommended this testing algorithm in 1995 (MMWR Mor Mortal Wkly Rep 1995;44:590-591). Although he had a positive IgM immunoblot in 2002, IgM positivity is only pertinent if a patient has been ill for ≤ 1 month. If a patient has been ill for more than a month, a positive IgG immunoblot is required. Without either a positive laboratory test on blood or CSF for Lyme disease, at or near the time that Mr Fix presented with optic neuritis, a diagnosis of Lyme disease as the explanation for the optic neuritis in this case is not tenable.

Therefore, with a reasonable degree of medical certainty, I conclude that Mr. Fix never had Lyme disease and that the episodes of optic neuritis were not due to Lyme disease.

Sincerely yours,


Gary P. Wormser, M.D.
Chief, Division of Infectious Diseases
Vice Chairman, Department of Medicine
Professor of Medicine and Pharmacology